

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

In re: MEDTRONIC, INC.,
IMPLANTABLE DEFIBRILLATORS
PRODUCTS LIABILITY LITIGATION

MDL No. 05-1726 (JMR/AJB)

This Document Relates to ALL ACTIONS

**MEDTRONIC, INC.'S MEMORANDUM IN SUPPORT OF MOTION TO
DISMISS THE MASTER CONSOLIDATED COMPLAINT FOR
MEDICARE AS SECONDARY PAYER ACT CLAIMS**

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INTRODUCTION

The Master Consolidated Complaint for Medicare as Secondary Payer Act Claims (“MSP Master Complaint”) asks this Court to apply a rarely used provision of the Medicare as Secondary Payer (“MSP”) statute, 42 U.S.C. § 1395y(b), in a manner never contemplated by Congress and rejected by every court to have considered the issue. The MSP statute was designed to “reduce Medicare costs by making the government a secondary provider of medical insurance coverage when a Medicare recipient has other sources of primary insurance coverage.” *Thompson v. Goetzmann*, 337 F.3d 489, 495 (5th Cir. 2003). It does this by creating a narrow cause of action against “primary plans” that had the primary responsibility to pay for medical costs but that failed to meet their obligation to do so. *See Mason v. American Tobacco Co.*, 346 F.3d 36, 42-43 (2d Cir. 2003); *Glover v. Philip Morris USA*, 380 F. Supp. 2d 1279, 1290-91 (M.D. Fla. 2005). This failure to meet a demonstrated obligation is the necessary trigger for bringing suit under the MSP statute. This trigger is indisputably absent here.

The MSP Master Complaint attempts to invoke the MSP statute against Medtronic Inc. (“Medtronic”)—the alleged “primary plan”—even though there has been no adjudication or other determination that Medtronic had a responsibility to reimburse Medicare. This puts the cart before the horse: how can Medtronic be liable for failing to reimburse Medicare when no responsibility to do so has been established? No court has allowed a suit under the MSP statute to survive a motion to dismiss where the alleged “primary plan” did not shirk a previously established obligation to reimburse Medicare.

See, e.g., Mason, 346 F.3d at 43; *Glover*, 380 F. Supp. 2d at 1291; *United States v. Philip Morris Inc.*, 156 F. Supp. 2d 1, 7-8 (D.D.C. 2001) (“*Philip Morris II*”); *United States v. Philip Morris Inc.*, 116 F. Supp. 2d 131, 135 (D.D.C. 2000) (“*Philip Morris I*”).

Merely being an alleged tortfeasor or having issued a warranty—which is all the MSP Master Complaint asserts about Medtronic—does not require reimbursement to Medicare. The unproven allegations of tort liability here stem from a February 2005 letter in which Medtronic advised physicians about a potential battery shorting mechanism that could occur in certain of its implantable cardioverter defibrillators (“ICDs”) and cardiac resynchronization therapy defibrillators (“CRT-Ds”) with batteries manufactured between April 2001 and December 2003. *See* Medtronic Mem. in Supp. of Mot. to Dismiss the Master Consolidated Complaint for Individuals (“Indiv. Mem.”) at 4-5.¹ The likelihood that the potential battery shorting mechanism would actually occur in a particular device was extremely remote, *see* Letter from Stan Myrum, Vice President, Medtronic, Inc., to Physicians (Feb. 2005) (Immelt Aff. Ex. A) (noting that the current rate of the shorting mechanism was .01%, and that highly accelerated bench testing indicates the rate “may increase to between 0.2 and 1.5% over the second half of the device life”), but Medtronic sought to allow physicians to make informed determinations about how best to manage the care of their individual patients who had potentially

¹ In order to streamline briefing, Medtronic adopts and incorporates fully by reference herein its Memorandum in Support of Motion to Dismiss the Master Consolidated Complaint for Individuals (“Indiv. Mem.”) and its Memorandum in Support of Motion to Dismiss the Master Consolidated Complaint for Third Party Payor Cases (“TPP Mem.”).

affected devices.² Medtronic accordingly offered to provide a replacement device when a patient and his or her physician determined that the implanted device should be replaced. *Indiv. Mem.* at 5-9. Most patients opted not to replace their devices. But even so, this good faith undertaking by Medtronic prompted nationwide litigation, including the meritless claims in the MSP Master Complaint.³

The MSP Master Complaint does not allege that a single implanted Medtronic defibrillator experienced premature battery depletion, much less that there was any injury because of it. Plaintiff Stubblefield instead seeks to use the MSP statute to adjudicate Medtronic's liability under state tort law, claiming that such liability will establish Medtronic's obligation to reimburse Medicare and make it liable for double damages, to boot. Stubblefield's interpretation would transform the MSP statute into a procedural and jurisdictional vehicle for allowing parties to assert disputed and unadjudicated garden-variety state-law tort claims in federal court. If this interpretation were correct, the MSP statute would allow any person to bring any sort of disputed state-law tort claim—from generic slip-and-fall claims to run-of-the-mill products liability claims—in federal court because of the fortuity of an injured party who happens to be a Medicare beneficiary.

² Because the MSP Master Complaint is expressly predicated in part on Medtronic's communication to physicians regarding the potential battery shorting mechanism, the Court may consider the content of the letter in which this information was communicated in ruling on Medtronic's motion to dismiss. *See Moses.Com Sec., Inc. v. Comprehensive Software Sys., Inc.*, 406 F.3d 1052, 1063 n.3 (8th Cir. 2005).

³ Medtronic moved on February 20, 2006 to strike all allegations in the various complaints relating to the "Class I Recalled ICDs." The Court should, for the reasons set forth in that motion, strike paragraphs 1 and 91-99 of the MSP Master Complaint and dismiss or sever any claims (as yet unasserted) that would arise from the "Class I Recalled ICDs."

The MSP statute was not intended to—and no court has ever interpreted it to—federalize state tort law in this manner.

The MSP Master Complaint should be dismissed for both jurisdictional and substantive reasons. To begin with, Stubblefield lacks standing to pursue the claims of the Complaint. Her claims are based on *no* injury-in-fact. Rather, her sole interest in prosecuting this case is a bounty, which is an insufficient interest to confer constitutional standing. *See Vermont Agency of Nat'l Res. v. United States ex rel. Stevens*, 529 U.S. 765, 772 (2000).

Stubblefield's claims also fail on the merits. Before a plaintiff can sue under the MSP statute, the defendant's responsibility to pay Medicare must have been established in some way—such as by an insurance contract, a settlement, or a judgment of tort liability. Medtronic has never been found liable for the Medicare expenditures that Stubblefield seeks to recover. And the MSP statute is not an open invitation to have a federal forum adjudicate state-law tort claims in the first instance.

The MSP Master Complaint therefore should be dismissed.

BACKGROUND

A. The MSP Statute

The MSP statute is designed to make Medicare the “secondary insurer” for its beneficiaries. *Mason*, 346 F.3d at 38; *Glover*, 380 F. Supp. 2d at 1282. This means that if a Medicare beneficiary has other medical insurance, the other insurance—and not Medicare—is supposed to be the primary payer of the medical bills. *Blue Cross and Blue Shield of Texas, Inc. v. Shalala*, 995 F.2d 70, 72 (5th Cir. 1993). The statute provides

that Medicare payment “may not be made . . . with respect to any item or service to the extent that payment has been made or can reasonably be expected to be made” under a “primary plan.” 42 U.S.C. § 1395y(b)(2)(A). Since the existence of other insurance coverage is sometimes unknown at the time of treatment, the MSP statute also authorizes conditional Medicare payments. 42 U.S.C. § 1395y(b)(2)(B)(i). The payment is “conditional” because if it turns out that there was a “primary plan” that should have covered the expense, that primary plan is required to reimburse the Medicare Trust Fund. 42 U.S.C. § 1395y(b)(2)(B)(ii).

The statute defines “primary plan” to include (1) “a group health plan or large group health plan”; and (2) “a workmen’s compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.” 42 U.S.C. § 1395y(b)(2)(A)(ii). It further provides that “[a]n entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance or otherwise) in whole or in part.” *Id.* If Medicare conditionally paid for services when a primary plan was “required or responsible . . . to make payment” under the statute, Medicare may seek reimbursement from the primary plan. 42 U.S.C. § 1395y(b)(2)(B)(iii).

The statute specifies how a primary plan’s responsibility for reimbursing Medicare may be demonstrated: by “(1) a judgment; (2) a payment conditioned upon the recipient’s compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the

primary plan or the primary plan's insured; or (3) by other means." *Id.*⁴ In other words, a primary plan is responsible for reimbursing Medicare when it was obligated to do so by a judgment, a settlement, or some other similar mechanism (such as an arbitration decision or administrative adjudication). *Glover*, 380 F. Supp. 2d at 1291 ("The 'by other means' language in section 1395y(b)(2)(B)(ii) encompasses other instances of 'like kind' where there is a previously established requirement or agreement to pay for medical services for which Medicare is entitled to be reimbursed.").

The MSP statute provides certain mechanisms for enforcing a primary plan's reimbursement obligation, including a cause of action by the government and a private cause of action. The private cause of action states:

There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

42 U.S.C. § 1395y(b)(3)(A). It is under this provision that Stubblefield purports to have standing to bring a claim against Medtronic in her self-proclaimed "representative capacity" as a "private attorney general." MSP Master Compl. at 1. In this capacity, she seeks to recover double the amount of *all* Medicare expenditures made on behalf of *all* Medicare beneficiaries in connection with the Marquis devices.

⁴ After numerous courts held that settlement of a tort claim did not constitute a "primary plan," *see, e.g., Thompson*, 337 F.3d at 504, the MSP was amended in 2003 to clarify, among other things, that Medicare had a right to reimbursement out of tort settlements. *See Glover*, 380 F. Supp. 2d at 1284-85 (citing H.R. Rep. No. 108-178(II), at 189-190 (2003); *Brown v. Thompson*, 374 F.3d 253, 262 (4th Cir. 2004) (citing same)).

B. Litigation Under The MSP Statute Of Unadjudicated Tort Claims

No court has found that a suit under the MSP statute involving unadjudicated tort claims validly states a claim. To the contrary, courts have consistently dismissed this type of claim—whether brought by the government or by individuals. For example, in *United States v. Philip Morris Inc.*, the government sought to recover double damages against tobacco companies that had not been found liable for medical expenditures nor entered into a settlement agreement with Medicare beneficiaries. 156 F. Supp. 2d at 2-3. The court dismissed the complaint, recognizing that imposing liability on alleged tortfeasors “would transform” the MSP provision into an “across-the-board procedural vehicle for suing tortfeasors.” *Id.* at 7-8. Similarly, in *Mason v. American Tobacco Co.*, the Second Circuit affirmed that tobacco companies were not subject to a suit brought by private plaintiffs under the MSP statute because the companies’ liability for Medicare costs had not yet been established. 346 F.3d at 43. As the court emphasized, “the trigger for bringing a MSP claim is not the pendency of a disputed tort claim”; rather, an MSP claim requires an “established obligation to pay medical costs pursuant to a pre-existing arrangement” in order to state a claim. *Id.*⁵

⁵ Congress amended the MSP while the *Mason* plaintiffs’ petition for rehearing was pending before the Second Circuit. The plaintiffs then moved to recall the mandate based on the 2003 amendments. The Second Circuit denied the motion, recognizing that the amendments did not alter the principle that governed the decision—MSP liability only attaches if an entity was *required* to pay under a primary plan. This principle was “inapplicable to the *alleged* tortfeasors in this case.” *Mason*, No. 02-7923, Order dated Jan. 16, 2004 (emphasis added) (available on PACER).

Most recently, in *Glover v. Philip Morris USA*, private plaintiffs attempted to bring a federal private right of action against tobacco manufacturers under the MSP statute. 380 F. Supp. 2d at 1288. As the *Glover* court described the case, “[p]laintiffs seek to use the private cause of action under the MSP [statute] to first establish defendants’ state law tort liability and then to seek reimbursement for Medicare payments made on account of that tortious conduct.” *Id.* The court dismissed the claims, holding that an alleged tortfeasor—“which has neither been adjudicated as liable nor has agreed to settle a tort claim”—neither currently has nor had in the past a responsibility to reimburse Medicare that it failed to meet. *Id.* at 1290. The court found that the language of the MSP statute commands three elements be met in order to state a claim: there must be “(1) a primary plan, (2) that is responsible to pay for an item or service, and (3) that failed to make the appropriate payment to Medicare for that item or service.” *Id.* But as the court recognized, there is no way that “an unliquidated, unadjudicated tort claim fits within the language of the MSP” provisions; nor is there any indication in the statute that Congress intended to allow a plaintiff to prove a defendant’s state law tort liability as part and parcel of the MSP private right of action. *Id.* at 1292.

C. The MSP Master Complaint⁶

The MSP Master Complaint was purportedly filed by Stubblefield “in her representative capacity as a ‘private attorney general.’ ” MSP Master Compl. at 1; *see*

⁶ Although Medtronic vigorously disputes that its products were defective or that its conduct was wrongful, it treats the allegations in the MSP Master Complaint as true (as it must) for purposes of this motion to dismiss. *Coons v. Mineta*, 410 F.3d 1036, 1039 (8th Cir. 2005).

also id. ¶ 7. Defendant Medtronic is a manufacturer of medical devices, including the defibrillator devices at issue in this case—known as the “Marquis devices”—with batteries that were manufactured between April 2001 and December 2003. *Id.* ¶¶ 2, 13-14, 100-101.⁷ Plaintiff Stubblefield seeks to recover twice the total amount of health care costs paid by Medicare in connection with the Marquis devices. *Id.* ¶¶ 7, 10. And yet, the Complaint is explicitly *not* for any personal injury Stubblefield allegedly suffered (MSP Master Compl. n.1 & ¶ 11); nor is there any allegation that any other identified individual was injured by any of the Marquis devices.

Instead, the Complaint alleges that Stubblefield is herself entitled to double damages for *all* Medicare expenditures related to the Marquis devices because Medtronic is a “primary plan” under the MSP. *Id.* ¶ 37. This assertion is not based on the existence of any judgment or settlement that imposed a reimbursement obligation on Medtronic and that Medtronic failed to fulfill. Stubblefield instead bases her claim of MSP liability on Medtronic’s February 2005 letter, which advised physicians about the remote possibility that the battery in the Marquis devices could short and offered to provide new Medtronic defibrillators free of charge to those who, based on consultation with their doctor, determined to have their device replaced, and on Medtronic’s offer to pay certain out-of-pocket medical expenses patients incurred in the course of replacing their Marquis

⁷ Defibrillators are implanted, programmable battery-operated devices that deliver a variety of therapies to patients suffering from chronic cardiac disease. *See* Indiv. Mem. at 4-6; TPP Mem. at 3-4. Like many medical devices, defibrillators have technological limitations—they require follow-up, reprogramming, and eventually, replacement. *See id.* Medicare—like any health insurer—therefore faces the periodic expense of removing an implanted device and replacing it with a new one.

device. *Id.* ¶¶ 2, 50, 100-101; *see* *Indiv. Mem.* at 7-9. Most patients opted not to replace their devices, but some did, and Medtronic provided replacement devices and paid for certain out-of-pocket expenses in keeping with its offer.

Plaintiff Stubblefield asserts three causes of action under the MSP statute, alleging that Medtronic is liable as a “first party insurer” for agreeing to pay certain out-of-pocket medical costs and for providing express and implied warranties (Counts One and Two) and as a “third party insurer” for having a liability insurance policy or plan or for being self-insured (Count Three). MSP Master Compl. ¶¶ 144-164. She further alleges eight state tort claims—also in her “representative capacity” as a “private attorney general”—including negligence (*id.* ¶¶ 165-173), strict liability for design and manufacturing defect (*id.* ¶¶ 174-184); strict liability for failure to warn (*id.* ¶¶ 185-191); breach of implied warranty (*id.* ¶¶ 192-196); breach of express warranty (*id.* ¶¶ 197-204); misrepresentation by omission (*id.* ¶¶ 205-211); violation of the Minnesota False Statement in Advertising Act (*id.* ¶¶ 212-217); and violation of the Minnesota Prevention of Consumer Fraud Act (*id.* ¶¶ 218-223).⁸

LEGAL STANDARDS

“Plaintiffs must adequately allege standing to bring their cases in federal court.” *Burton v. Central Interstate Low-Level Radioactive Waste Compact Comm’n*, 23 F.3d 208, 209 (8th Cir. 1994). “[I]f a plaintiff lacks standing, the district court has no subject

⁸ The MSP Master Complaint is silent on what statutory basis allegedly grants Stubblefield the authority to bring state-law tort claims as a “private attorney general.”

matter jurisdiction.” *Young Am. Corp. v. Affiliated Computer Servs., Inc.*, 424 F.3d 840, 843 (8th Cir. 2005) (quotation omitted). Thus, when a “plaintiff offers no factual allegations, specific or general, demonstrating an injury in fact, the court should dismiss the claim.” *Id.*

Dismissal for failure to state a claim is appropriate when “it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.” *Crumpley-Patterson v. Trinity Lutheran Hosp.*, 388 F.3d 588, 590 (8th Cir. 2004). “[T]he complaint must contain sufficient facts, as opposed to mere conclusions, to satisfy the legal requirements of the claim to avoid dismissal.” *DuBois v. Ford Motor Credit Co.*, 276 F.3d 1019, 1022 (8th Cir. 2002). While the Court must credit alleged facts as true, *Coons*, 410 F.3d at 1039, it is “free to ignore legal conclusions, unsupported conclusions, unwarranted inferences and sweeping legal conclusions cast in the form of factual allegations.” *Farm Credit Servs. of Am. v. American State Bank*, 339 F.3d 764, 767 (8th Cir. 2003).

ARGUMENT

I. THE MSP CLAIMS MUST BE DISMISSED BECAUSE PLAINTIFF STUBBLEFIELD LACKS STANDING TO BRING THEM.

“A party invoking the jurisdiction of the federal courts must meet the constitutional requirements of Article III and the prudential limitations crafted by the courts.” *United States v. United Sec. Sav. Bank*, 394 F.3d 564, 567 (8th Cir. 2004). Only if both “constitutional limitations on federal-court jurisdiction and prudential limitations on its exercise” are satisfied is a litigant “entitled to have the court decide the merits of

the dispute or of particular issues.” *Warth v. Seldin*, 422 U.S. 490, 498 (1975); *see also Trump Hotels & Casino Resorts, Inc. v. Mirage Resorts Inc.*, 140 F.3d 478, 484 (3d Cir. 1998) (“Standing ‘subsumes a blend of constitutional requirements and prudential considerations.’ ”) (quoting *Valley Forge Christian Coll. v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 471 (1982)). Stubblefield meets neither the Article III nor the prudential standing requirements.

A. Stubblefield Lacks Article III Standing To Sue Under The MSP Statute Because She Has Not Alleged An Injury-In-Fact.

“To show standing under Article III of the U.S. Constitution, a plaintiff must demonstrate (1) injury in fact, (2) a causal connection between that injury and the challenged conduct, and (3) the likelihood that a favorable decision by the court will redress the alleged injury.” *Young Am. Corp.*, 424 F.3d at 843 (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). As the Eighth Circuit has emphasized, an injury-in-fact cannot be “conjectural or hypothetical.” *McClain v. American Economy Ins. Co.*, 424 F.3d 728, 731 (8th Cir. 2005) (quoting *Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-181 (2000)). Instead, it must be “direct,” “concrete and particularized,” and “actual or imminent.” *Id.* (quoting *Friends of the Earth*, 528 U.S. at 180-181); *Steger v. Franco, Inc.*, 228 F.3d 889, 892 (8th Cir. 2000). Even when purporting to confer a statutory private right of action, Congress cannot manufacture Article III standing for a plaintiff who otherwise has no injury. *See Raines v. Byrd*, 521 U.S. 811, 820 n.3 (1997) (“It is settled that Congress cannot erase Article III’s

standing requirements by statutorily granting the right to sue to a plaintiff who would not otherwise have standing.”).

Stubblefield fails to allege that she suffered any injury-in-fact. She alleges that she had a Marquis device implanted and subsequently explanted, but she does not allege that her Marquis device ever operated improperly. Nor does the Complaint allege that she incurred any financial injury, since Medicare paid her medical expenses. *See, e.g., Wheeler v. Travelers Ins. Co.*, 22 F.3d 534, 538 (3d Cir. 1994) (when Medicare pays the medical expenses that plaintiff asserts should have been paid by another, plaintiff suffers no actual or threatened injury). And even more to the point, Stubblefield expressly excludes any allegation of personal injury to her from the MSP Master Complaint, reserving it instead for the Individual Master Complaint. *See* MSP Master Compl. n.1 & ¶ 11. The only “injury” alleged in the MSP Master Complaint is to the Medicare fisc—and Stubblefield has no more claim to be “injured” in that respect than any other taxpayer in the country. *See Booth v. Hvass*, 302 F.3d 849, 851-852 (8th Cir. 2002) (“a federal taxpayer’s interest in United States treasury funds is too small and indeterminable to give that taxpayer standing to sue in federal court”) (citing *Frothingham v. Mellon*, 262 U.S. 447, 487 (1923)).⁹

Allowing Stubblefield to maintain a cause of action under the MSP statute would violate the principle that “a plaintiff’s complaint must establish that he has a ‘personal

⁹ There also is no plausible way to allege the United States has suffered an injury-in-fact here because Medtronic’s obligation to reimburse Medicare has not yet been—and may never be—demonstrated.

stake’ in the alleged dispute, and that the alleged injury suffered is particularized to him.” *Raines*, 521 U.S. at 818-819. Stubblefield may argue that her “personal stake” in the dispute is the lucrative financial reward she seeks—twice the total of *all* Medicare expenditures involving the Marquis devices at issue. But this too fails to amount to an injury-in-fact. In *Vermont Agency of Natural Resources*, 529 U.S. at 772, the Supreme Court made clear that an interest in “the bounty [a plaintiff] will receive if the suit is successful” is merely a “concrete private interest in the outcome of [the] suit”—similar to “someone who has placed a wager upon the outcome.” An interest in a bounty is therefore unrelated to injury-in-fact and “insufficient to give a plaintiff standing.” *Id.*; see also *Warth v. Seldin*, 422 U.S. 490, 499 (1975) (“The Article III judicial power exists only to redress or otherwise to protect against injury *to the complaining party*.”) (emphasis added).¹⁰

Nor does Stubblefield’s assertion to be suing in her “representative capacity” as a self-appointed “private attorney general” provide her with the required Article III injury-in-fact. As a threshold matter, the MSP statute makes no reference to a “private attorney general.” And even when statutes do enable individuals to be “private attorneys general,” those individuals still must independently satisfy the standing requirements of Article III, *i.e.*, they must have suffered a redressable injury-in-fact fairly traceable to the defendant’s conduct. See, e.g., *Association of Community Orgs. for Reform Now v.*

¹⁰ In the False Claims Act context, where the relator is an assignee, the relator has Article III standing to assert the injury-in-fact suffered by the assignor. *Vermont Agency of Natural Resources*, 529 U.S. at 773 (explaining that the statute’s *qui tam* provision “effect[s] a partial assignment of the Government’s damages claim”).

Fowler, 178 F.3d 350, 365 (5th Cir. 1999) (while a private attorney general enforcement mechanism can eliminate prudential standing requirements, it cannot eliminate Article III standing requirements). Moreover, unlike the *qui tam* context, the MSP statute not provide for assignment of the government's claim to an individual. Stubblefield tellingly never asserts to be an assignee, and her Complaint is not styled "United States ex rel. Billie Stubblefield."

Ultimately, Stubblefield seeks to recover all Medicare expenditures made by Medicare on behalf of herself *and* all other Medicare beneficiaries simply because Medtronic advised physicians that bench testing showed a remote possibility of premature battery depletion. The MSP Master Complaint contains no non-hypothetical, non-conjectural allegation of any injury-in-fact, and for this reason alone should be dismissed for lack of subject matter jurisdiction. *See, e.g., In re Operation of Missouri River Sys. Litig.*, 421 F.3d 618, 637 (8th Cir. 2005) (affirming dismissal for lack of Article III standing where complaint failed to "set forth a 'concrete and particularized' injury that is likely to be redressed by" the relief sought) (quoting *Lujan*, 504 U.S. at 560-561).

B. Stubblefield Also Lacks Prudential Standing.

"Prudential principles of standing are statutorily imposed jurisdictional limitations separate from and in addition to constitutional standing requirements." *Davis v. U.S. Bancorp*, 383 F.3d 761, 767 (8th Cir. 2004); *see also Mosby v. Ligon*, 418 F.3d 927, 933 (8th Cir. 2005) ("In addition to satisfying Article III standing requirements, litigants must stay within 'prudential limitations' on the exercise of federal-court jurisdiction.")

(citing *Warth*, 422 U.S. at 498 (1975)). There are three basic requirements for prudential standing. First, a litigant must “assert his [or her] own legal interests rather than those of third parties.” *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 804 (1985); *Mosby*, 418 F.3d at 933. Second, when the only asserted harm is a “generalized grievance” rather than a unique stake in the controversy, “that harm alone normally does not warrant exercise of jurisdiction.” *Warth*, 422 U.S. at 499. And third, a litigant must demonstrate that her interests are within “the zone of interests” intended to be protected by the statute on which the claim is based. *Valley Forge Christian Coll.*, 454 U.S. at 475 (1982).

Stubblefield fails the prudential standing requirements. She fails the first requirement because she purports to assert *only* the “legal interests” of third parties—not her own. And she fails the second requirement for similar reasons: she asserts only a “generalized grievance,” traceable to no “unique stake” in the controversy, regarding Medicare’s expenditures for particular devices. Thus even if it could be said (on the most general level imaginable) that Stubblefield’s interests are theoretically within the “zone of interests” potentially protected by the MSP statute, she cannot satisfy the other prudential standing factors.

Stubblefield claims she is a “representative” of the government and “all other Medicare beneficiaries,” entitled to all of the relief allegedly due Medicare for certain payments made on behalf of all beneficiaries. MSP Master Compl. at 1. The MSP statute does not support that contention. A plaintiff’s prudential standing depends in part on “whether the constitutional or statutory provision on which the claim rests properly can be understood as granting” the plaintiff a right to the judicial relief she seeks. *Warth*,

422 U.S. at 500. Here, there is no indication that Congress has granted, either “expressly” or by “clear implication,” *id.* at 501, one individual the right to bring suit on behalf of all other Medicare beneficiaries and the United States itself. The MSP statute says only that it “establishe[s] a private cause of action for damages” in circumstances where “a primary plan . . . fails to provide for primary payment (or appropriate reimbursement).” 42 U.S.C. § 1395y(b)(3)(A). *See Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) (explaining that the meaning of any statute is found first and foremost in the words chosen by Congress in drafting the statute); *cf. In re Baycol Prods. Litig.*, MDL 1431, 2004 WL 1078717, *3 (D. Minn. Apr. 13, 2004) (unpublished decision) (declining to address whether a private plaintiff has standing to represent the claims of the United States or other Baycol plaintiffs under the MSP statute, but observing that “the private right of action provided in the MSP does not provide that such an action is brought on behalf of the United States”).¹¹

Congress knows how to provide for expansive prudential standing when it so intends. For example, the False Claims Act expressly authorizes a private party to bring a *qui tam* action “for the person and for the United States government”—and the suit is brought “in the name of the government.” 31 U.S.C. § 3730(b)(1). In that type of situation, where the government is allowing a private party to litigate its rights, Congress

¹¹ Stubblefield’s theory of prudential standing makes no sense as a practical matter. If Stubblefield has the right to obtain adjudication of every other Medicare beneficiary’s right to recover under the MSP statute—and to arrogate to herself any damages due under the MSP—she would effectively preclude every other Medicare beneficiary, not to mention the federal government, from bringing a similar suit or sharing in the bounty.

has ensured that a panoply of procedural mechanisms are in place to protect the government's interests. These procedural protections include, but are not limited to:

- (1) mandating that a private *qui tam* plaintiff serve the complaint and written disclosure of material evidence on the government before the complaint is served on the defendant;
- (2) requiring that the complaint be filed in camera, remain under seal for at least 60 days while the government conducts an investigation, and not be served on the defendant except by court order;
- (3) requiring that the government either intervene and take over the conduct of the action before the defendant is served or notify the court that the private person will be conducting the action;
- (4) ensuring that if the government "proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action";
- (5) allowing the government to dismiss or settle the action over the objection of the private citizen who filed the action;
- (6) allowing the court to limit any participation by the person initiating the action if the government shows that such participation would interfere with or unduly delay the government's prosecution of the case or would be repetitious, irrelevant, or for purposes of harassment;
- (7) allowing the government, even if it does not take over conduct of the action, to request it be served with copies of all pleadings and deposition transcripts and to request a stay of discovery if discovery would interfere with the investigation or prosecution of a matter arising out of the same facts;
- (8) mandating that the government provide written consent with its reasons for consenting before the case can be dismissed;
- (9) protecting the government from any liability for expenses the relator incurs in bringing a *qui tam* suit; and
- (10) ensuring that the government receives at least 70-85% of any recovery.

31 U.S.C. § 3730(b)-(f). The MSP, in sharp contrast, contains *none* of these procedural protections—further underscoring Stubblefield’s lack of standing to bring suit on behalf of the United States.¹²

The absence of express or implied statutory authorization to bring a private cause of action on behalf of all Medicare beneficiaries at large, or on behalf of the United States, together with the lack of procedural protections of the government’s interests, supports only one conclusion. A private plaintiff who can establish a redressable Article III injury has—at most—prudential standing under the MSP to sue for those expenditures associated with that plaintiff’s *own* medical care. The MSP Master Complaint, which fails both the Article III and prudential standing inquiries, should be dismissed.

C. Any Claim Brought Under The MSP Statute Is Not Ripe.

Their substantial standing problems aside, Stubblefield’s claims are also, at best, premature. Standing and ripeness are related doctrines “in that each focuses on ‘whether the harm asserted has matured sufficiently to warrant judicial intervention.’ ” *United States v. McAllister*, 225 F.3d 982, 990 (8th Cir. 2000) (quoting *Warth*, 422 U.S. at 499 n.10). Stubblefield’s theory of recovery under the MSP statute depends on Medtronic having failed to meet an obligation to reimburse Medicare—an obligation that has never been demonstrated by a judgment, settlement, or similar means and remains a matter very much in dispute. But as the text of the MSP statute makes clear, unless and until Medtronic’s obligation to reimburse Medicare is “demonstrated” by a judgment,

¹² Stubblefield in fact asserts that the government “has no authority to intervene to the exclusion of the Plaintiff in this private right of action.” MSP Master Compl. ¶ 32.

settlement, or similar means, 42 U.S.C. § 1395y(b)(2)(B)(ii), and Medtronic defaults on that obligation, there is no cause of action to bring. *Nebraska Pub. Power Dist. v. MidAm. Energy Co.*, 234 F.3d 1032, 1037-38 (8th Cir. 2000). Accordingly, in addition to its other infirmities, the MSP Master Complaint should be dismissed as unripe.

II. THE MSP CLAIMS FAIL TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED.

Stubblefield has not—and cannot—allege any judgment, settlement, or similar resolution of any tort claims against Medtronic that would establish a responsibility to reimburse Medicare. Stubblefield instead contends that the MSP is a procedural device allowing her to bring a massive quasi-class action in federal court—notably not subject to Rule 23—against Medtronic to determine state-law liability and MSP liability at the same time. She states that “[f]or purposes of Medicare’s right to recovery, the MSP does not distinguish between, but encompasses, both ongoing litigation against primary plans and settled claims paid by primary plans.” MSP Master Compl. ¶ 36. This interpretation of the MSP would result in a revolutionary change in federal jurisdiction, radically federalizing state tort law any time a Medicare beneficiary is involved. And it would make no sense: to avoid liability for double damages, a company like Medtronic would have to “reimburse” Medicare at the drop of a hat anytime any Medicare beneficiary alleged tort liability—without the right ever to contest the allegations, however frivolous. As the *Glover* court recognized, the plain text of the MSP squarely refutes Stubblefield’s unprecedented interpretation of the statute. 380 F. Supp. 2d. at 1290 (MSP cause of

action requires “(1) a primary plan, (2) that is responsible to pay for an item or service, and (3) that failed to make the appropriate payment to Medicare for that item or service”).

All of Stubblefield’s MSP claims should be dismissed pursuant to Rule 12(b)(6).

A. The MSP Master Complaint Does Not Allege That Medtronic Has Or Had A Demonstrated Responsibility To Reimburse Medicare.

Stubblefield alleges that Medtronic is a “primary plan” that is in breach of its responsibility to reimburse Medicare for “health care costs resulting from the Recalled ICDs.” MSP Master Compl. ¶ 37. She offers three theories for Medtronic’s MSP liability: (1) Count One, “Liability as First Party Insurer Under MSP: Agreement to Pay Medical Costs (*id.* ¶¶ 144-150)”; (2) Count Two, “Liability as First Party Insurer Under MSP: Provision of Express and Implied Warranties” (*id.* ¶¶ 151-157); and (3) Count Three, “Liability as Third Party Insurer Under MSP: Liability as Holder of a Liability Insurance Policy or Plan” (*id.* ¶¶ 158-164).¹³

All of these theories suffer from the same fatal flaw. Any reimbursement obligation under the MSP statute only arises after it has been demonstrated by “a judgment, a payment conditioned upon the recipient’s compromise, waiver, or release (whether or not there is an admission of liability) [i.e., a settlement], or by other means” that a primary plan “has or had a responsibility to make payment” to Medicare. 42 U.S.C.

¹³ Stubblefield distinguishes between what she calls “first party insurance coverage” and “third party (tortfeasor) insurance coverage.” But her concepts of “first party insurance coverage” and “third party (tortfeasor) insurance coverage” do not appear anywhere in the MSP statute.

§ 1395y(b)(2)(B)(ii). No such judgment, settlement, or other means of demonstrating Medtronic has or had a reimbursement obligation exists.¹⁴

Stubblefield asserts three possible theories of “other means” by which to establish Medtronic’s payment obligation. *First*, she relies on Medtronic’s voluntary offer “to provide un-reimbursed medical expenses (after Medicare payments) to patients for out-of-pocket expenses up to \$2,500.” MSP Master Compl. ¶ 50. The Complaint highlights that Medtronic did not offer to pay for any care that would be paid for by medical insurance providers or Medicare. *Id.* ¶¶ 51-52, 55, 58. It is entirely illogical to rely on Medtronic’s offer to cover some amount of “unreimbursed” medical expenses as having demonstrated the company’s responsibility to pay for medical expenses that are (and should have been) paid for by Medicare.

Second, Stubblefield proffers that the fact of Medtronic’s voluntary offer “to provide a replacement device” demonstrated its responsibility to reimburse Medicare. MSP Master Compl. ¶ 50. According to Stubblefield, the offer of a replacement device was part of a “warranty” by Medtronic. *Id.* ¶ 58. But there is no allegation that the scope of any purported warranty covered medical expenses. Providing a replacement medical device as part of a warranty program in no way translates into having a “demonstrated . . . responsibility” for reimbursing Medicare.

¹⁴ This demonstrated reimbursement obligation is required to state a claim under any theory of MSP liability; thus, failure to satisfy this element defeats both Stubblefield’s “first party insurance” and her “third party (tortfeasor) insurance” claims.

Third, Stubblefield asserts Medtronic's "demonstrated . . . responsibility" stems from the fact that "Medtronic maintains a liability insurance program, or is self-insured, from which payments for medical costs are made *once liability has been established*." *Id.* ¶ 160 (emphasis added). The problems with this theory are obvious. The mere fact that a company maintains a liability insurance policy or is self-insured cannot possibly mean that a responsibility to reimburse Medicare has been "established," especially when, as in this case, liability has *never* been established.

None of these theories show that Medtronic had—and failed to honor—a demonstrated responsibility to reimburse Medicare. The court's decision in *Glover* is on all fours with this case. In *Glover*, private plaintiffs attempted to bring an MSP cause of action in which they sought first to establish the defendant's state tort liability and then to obtain the benefit of reimbursed Medicare payments made on account of that allegedly tortious conduct. 380 F. Supp. 2d at 1289-92. The court dismissed the claims, holding that plaintiffs could not rely on "unresolved, unestablished tort claims" to demonstrate the defendant's liability under the MSP. *Id.* at 1291. As a matter of logic and common sense, "it cannot be 'demonstrated' that an alleged tortfeasor, which has neither been adjudicated as liable nor has agreed to settle a tort claim, 'has' an existing 'responsibility' to reimburse Medicare or 'had' a previous responsibility to do so. *Id.* at 1290.

As every other court to address this issue has ruled, a plaintiff cannot show that an *alleged* tortfeasor like Medtronic has or had a demonstrated responsibility to pay for items or services for which Medicare made a conditional payment. Stubblefield, however, boldly asserts that "[f]or purposes of Medicare's right to recovery, the MSP does not

distinguish between, but encompasses, both ongoing litigation against primary plans and settled claims paid by primary plans.” MSP Master Compl. ¶ 36. This statement is patently wrong. Although *Stubblefield* cites § 1395y(b)(2)(B)(ii) as support, neither this nor any other provision of the MSP addresses “ongoing litigation against primary plans.” And no court has ever accepted such a proposition. *See, e.g., Mason*, 346 F.3d at 43 (“the trigger for bringing an MSP claim is not the pendency of a disputed tort claim, but the established obligation to pay medical costs pursuant to a pre-existing arrangement to provide insurance benefits”); *Glover*, 380 F. Supp. 2d at 1295 (“The language of the MSP . . . simply does not support [a] private cause of action where the underlying tort liability and defendants’ responsibility to pay Medicare has not been established by judgment, settlement, or other means of like kind.”) (internal quotation marks and citation omitted); *see also United States v. Baxter Int’l, Inc.*, 345 F.3d 866 (11th Cir. 2003) (Medicare is entitled to reimbursement from mass-tort settlement fund that assumed the obligation to pay for medical costs of plaintiff class members).

Notably, the Centers for Medicare and Medicaid Services (“CMS”)—the government agency that administers the Medicare program—does not take the position that a disputed tort claim creates liability under the MSP statute:

In MSP liability situations, before a settlement is reached between the beneficiary and the liable party or a court renders a judgment, there is no overpayment. Medicare’s claim comes into existence by operation of law when payment for medical expenses that Medicare conditionally paid for has been made by a third party payer. Consequently, while Medicare may alert beneficiaries and their attorneys of Medicare’s right to recover settlement proceeds in pre-

settlement correspondence, no demand for recovery may be made until a settlement has been reached.

See Medicare Secondary Payer (MSP) Manual, CMS Pub. 100-05, Chapter 7: Contractor MSP Recovery Rules § 50.4.1 (Rev. 25, Effective Apr. 25, 2005) (Internet Only Manual), available at <http://www.cms.hhs.gov/manuals/downloads/msp105c07.pdf>.

Simply put, the MSP statute is not a mechanism for adjudicating tort liability. It establishes a potential obligation to repay Medicare as a consequence of the outcome of such adjudication, but has no relevance in the context of a products liability claim unless and until the plaintiff has won the case or the claim has been settled.

B. Stubblefield's "Warranty" Theory Of MSP Liability Fails To State A Claim.

Counts One and Two, which allege Medtronic is a "first party insurer," also fail to state a claim for an independent reason. These two counts are premised on Medtronic's offer to provide replacement Marquis devices at no cost and to pay some of patients' out-of-pocket medical expenses. According to Stubblefield, this offer is a "warranty" that transforms Medtronic into a "first party insurer" with a reimbursement obligation. MSP Master Compl. ¶ 44 ("Medtronic is a primary payer under MSP's first party insurer provisions. Medtronic has *agreed* to make payment of out of pocket expenses as *part of its extended warranty* programs.") (emphases added). However, this allegation is wrong as a matter of law. Even the Complaint itself identifies "first party insurance" under the statute as including "group health plans, large group health plans, workmen's compensation plans and no-fault insurance." *Id.* ¶ 35.

There is no dispute that Medtronic voluntarily offered in 2005 to provide replacement devices at no cost when the patient and his or her physician deemed explantation medically appropriate, and to pay certain associated out-of-pocket medical expenses. *See* Letter from Stan Myrum, Vice President, Medtronic, Inc., to Physicians (Feb. 2005) (Ex. A). But as a matter of law, such offers do not constitute a “primary plan” under the MSP. The statute specifies that “the term ‘primary plan’ means ‘a group health plan or large group health plan’ and ‘a workmen’s compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance.’” 42 U.S.C. § 1395y(b)(2)(A)(ii). It is self-evident that this definition of “primary plan” does not include “warranties” within its scope. Nor can warranties be implicitly read into the scope of the provision because none of the terms used—group health plans, automobile insurance, liability insurance, and no fault insurance—fairly encompass warranties within their plain meaning. *See Robinson v. Shell Oil Co.*, 519 U.S. 337, 340 (1997) (holding that a statute’s meaning is found first and foremost in the words chosen by Congress in drafting the statute). Medtronic is not aware of *any* authority that has ever indicated a warranty constitutes a “primary plan” under the MSP statute.¹⁵

Because the alleged “warranty” does not meet the clear statutory definition of “primary plan,” Stubblefield’s theory of MSP liability as a first party insurer fails as a matter of law.

¹⁵ A warranty also could never constitute the obligation Stubblefield asserts—payment of all medical expenses covered by Medicare—because any warranty would be limited to its terms.

III. THE MSP STATUTE DOES NOT AUTHORIZE STUBBLEFIELD TO ASSERT STATE TORT CLAIMS AGAINST MEDTRONIC, AND IN ANY EVENT, THOSE CLAIMS FAIL TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED.

The MSP statute does not authorize the government or a private party to bring state law tort claims for negligence, strict liability, breach of warranty, misrepresentation, false advertisement, or consumer fraud (Counts Four to Eleven). Because Stubblefield is purporting to pursue the MSP Master Complaint solely as a “private attorney general,” she cannot proceed on state tort claims unless those claims are authorized to be brought by someone acting in that capacity. No such authorization exists. The state tort claims in Stubblefield’s Complaint are apparently included as part of Stubblefield’s mistaken belief that an MSP complaint is the proper place to prove—in the first instance—Medtronic’s liability for failing to reimburse Medicare. As we have shown, that theory is not supported by the statute or any case to have decided the issue. And in any event, as explained in detail in Medtronic’s motions to dismiss the Individual and TPP Master Complaints, each of these state tort law claims is without merit. *See* Individ. Mem. 11-40; TPP Mem. 15-31.

CONCLUSION

For all of the foregoing reasons, the MSP Master Complaint should be dismissed with prejudice in its entirety.

Respectfully submitted,

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